NDA 21-036/SLR-004

Glaxo Wellcome, Inc. 27 APR 2001
Attention: Sherman N. Alfors
Project Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your Labeling Supplement-Changes Being Effected, dated March 20, 2001, received March 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Relenza® (zanamivir for inhalation).

This Labeling Supplement-Changes Being Effected provides for the addition of "facial edema" to the *Adverse Reactions: Observed During Clinical Practice* section of the package insert.

We have completed review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Virginia L. Yoerg, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation 4
Center for Drug Evaluation and Research